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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,414	02/25/2004	Juergen Roemisch	06478.1447-01	8362

22852 7590 12/29/2005

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EXAMINER
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SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/785,414

Applicant(s)

ROEMISCH ET AL.

Examiner

Michael Szperka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-29 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 13-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 12 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/635,468.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/18/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This application is a continuation of USSN 09/635,468 filed 8/11/2000 which claims foreign priority to German document 19937656.5 filed 8/13/1999.

Claims 9-29 are pending in the instant application.

Applicant's election with traverse of the disease species systemic lupus erythematosus (SLE) as it reads on claims 9, 11, 12, and 27-29 in the reply filed on October 13, 2005 is acknowledged. The traversal is on the ground that there is no search burden. This is not found persuasive because of the reasons of record set forth in the restriction requirement mailed August 22, 2005.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10 and 13-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Applicant timely traversed the restriction (election) requirement in the reply filed on October 13, 2005.

The examination of claims 9, 11, 12, and 27-29 under the statutes of 35 USC 101, 102, 103, and 112 are under examination as they read on the elected species SLE.

***Information Disclosure Statement***

2. Applicant's IDS received May 18, 2004 is acknowledged and has been considered. Foreign patent documents DE 43 03 646 and EP 0 629 406 have been lined through and not considered because the examiner cannot read German and no translation of the documents has been provided. The listed European search reports have been considered but lined through because such documents are not appropriate for inclusion on the printed face of a US patent.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 9, 11, 12, and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimamoto et al. (Internal Medicine, 1992, 31:1392-1395, see entire document) as evidenced by Beall et al. (JAMA, 1975, 234:518-519, see entire document).

Shimamoto et al. teach the administration of antithrombin III (AT III) to a patient suffering from SLE (see entire document, particularly the abstract and the left column of page 1393).

It is noted that Shimamoto et al. do not teach that AT III reduces chemokine-mediated migration of leukocytes in an SLE patient. However, in performing the method taught by Shimamoto et al. one administers the same compound (AT III) to the same patient population (SLE) as is recited in the instant claimed methods. As such, it is inherent that a patient would gain all of the therapeutic benefits recited in the instant claimed method when performing the prior art method though by Shimamoto et al. since the method steps are the same.

It is also noted that a dependent claim indicates that AT III is to be administered by a variety of routes. Shimamoto et al. do not explicitly indicate the route by which they administered AT III, but the AT III taught by Shimamoto et al. was administered intravenously. This is because it is standard to treat SLE patients with intravenous medications as is taught by Beall et al. (see entire document, particularly the paragraph that spans pages 518 and 519, and the Figure) and because treatments of systemic diseases are best done intravenously since the therapeutic agent can be rapidly conveyed to all parts of the body.

Therefore, the prior art anticipates the claimed invention.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 9, 11, 12 and 27-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,399,572. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more narrow in that the list of diseases that are treated or cured are a subset of those currently recited in the instant claims. Note that the patented claims recite the elected disease species of SLE (see particularly patented claims 3 and 6), and that reducing chemokine migration of neutrophils is an inherent property that arises from the *in vivo* administration of AT III as was discussed above. As such, the patented claims anticipate the broader instant claims.

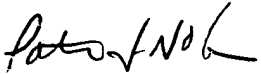
7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.  
Patent Examiner  
Technology Center 1600  
December 12, 2005

  
Patrick J. Nolan, Ph.D.  
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12/23/05